

**REMARKS**

Claims 1 and 12-25 are pending. Claims 1, 14, 16, 17, 19-22 and 25 are withdrawn from examination. Claim 12 has been amended to clarify the claimed invention. New claims 26-28 have been added. Support for new claims 26-28 can be found, for example, in original claims 15, 23 and 24. No new matter has been added by either the amendment to pending claim 12 or the new claims and entry thereof is respectfully requested. Upon entry of this amendment, claims 12, 13, 15, 18, 22-25 and 26-28 will be pending and under examination...

Claim 12 has been amended merely to clarify the claimed invention without changing the claim's scope. New claims 26-28 have been added. Support for new claims 26-28 can be found, for example, in original claims 15, 23 and 24. Accordingly, these amendments and new claims do not raise an issue of new matter and entry thereof is respectfully requested.

**Regarding 35 U.S.C. § 112, Second Paragraph**

The rejection of claims 12, 13, 15, 18, 23 and 24 under 35 U.S.C. § 112, second paragraph, for allegedly failing to point out and distinctly claim the subject matter regarded as the invention, respectfully is traversed. Nevertheless, this rejection has been rendered moot by the amendment to claim 12, which now recites that the enzyme "when stored" shows no loss or less than 20% loss of activity after prolonged storage. Accordingly, removal of this rejection is respectfully requested.

**Regarding 35 U.S.C. §102**

The rejection of claims 12, 15, 23 and 34 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 2,774,673, ("Young") is respectfully traversed.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Examiner must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

The invention of independent claim 12 is a method for storing an enzyme that encompasses adding to the enzyme a food color, wherein the enzyme, when stored, shows no loss or less than 20% loss of activity after prolonged storage.

Young describes the a mixture of proteolytic enzymes, monosodium glutamate, carbohydrates, and condiments (pepper and paprika), and salt. C.2:14-29.

Young describes that black pepper and paprika are added as condiments having anti-oxidative qualities. C.1:50-51. Young does not suggest, much less describe, adding to an enzyme a food color.

Young describes that the mixture has a shelf life of "substantial potency" of more than 12 months. C.2:52-54. Young does not quantify "substantial potency." Young et al. does not suggest, much less describe, a loss of 20% or less after prolonged storage.

Young describes a mixture of 8 distinct components, one of which is papain. Young describes that, together, the 8 distinct components of the mixture, each in a narrow percent of total weight range, has a substantial shelf life. C.2:36-72. Young does not suggest, much less describe, a method for adding to an enzyme a food color, wherein the addition of **one** component, a food color, results in the stored enzyme having no loss or less than 20% loss of activity after prolonged storage.

As described above, Young fails to teach all the elements of the claimed invention and, therefore, Young cannot support the required *prima facie* case of anticipation for which it is cited. Accordingly, removal of the rejection of claims 12, 15, 23 and 34 under 35 U.S.C. §102(b) as being anticipated by Young is respectfully traversed.

#### **Regarding 35 U.S.C. §103**

The rejection of claims 12, 15, 23 and 24 under 35 U.S.C. §103(a) as being unpatentable over Young is respectfully traversed.

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. 35 U.S.C. § 103(a) (2000); *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966). Recently, the U.S. Court of Appeal for the Federal Circuit reiterated the proper standards for making determinations under § 103. *In re Kahn*, 441

F.3d 977 (Fed. Cir. 2006). First, the scope and content of the prior art is determined, the differences between the prior art and the claims at issue are ascertained along with the level of ordinary skill in the pertinent art. Against this background, a determination is made whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. *Id.* at 985 (citing *Dann v. Johnston*, 425 U.S. 219, 226 (1976) and *Graham v. John Deere Co.*, 383 U.S. 1, 13-14 (1966)).

Applicants respectfully maintain that the Office has not met the burden the law allocates to it with regard to establishing a *prima facie* case of obviousness, which requires that the **combination of references relied upon teaches or suggests all limitations** of the claims and that the prior art references relied upon give rise to the **requisite motivation to combine their content**, and that when viewed in combination, provide the skilled person with a reasonable expectation of success to achieve the claimed invention. The Federal Circuit has repeatedly held that even where all claim limitations are found in a number of prior art references, the a motivation to combine the particular teachings from different references must nevertheless be shown. *In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004).

As set forth above in rebutting the novelty rejection, Young fails to teach the following elements of the claimed invention:

- (1) Young does not describe or suggest adding to an enzyme a food color.
- (2) Young et al. does not describe or suggest a loss of 20% or less after prolonged storage.
- (3) Young does not describe or suggest a method for adding to an enzyme a food color, wherein the addition of **one** component, a food color, results in the stored enzyme having no loss or less than 20% loss of activity after prolonged storage.

In addition to not teaching or suggesting all of the elements of the claimed invention, Young does not provide the requisite modification to modify its teachings so as to arrive at the claimed invention. Motivation is considered to be lacking where, as here, the state of the art at the time of the invention pointed the skilled person in a different direction than the inventor proceeded. Indeed, the Federal Circuit has repeatedly recognized that proceeding contrary to the

accepted wisdom in the art represents "strong evidence of unobviousness." *In re Hedges*, 783 F.2d 1038, 1041, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552, 220 U.S.P.Q. 303, 312 (Fed. Cir. 1983)(prior art teaching that conventional polypropylene should have reduced crystallinity before stretching and should undergo slow stretching led away from claimed process of producing porous article by expanding highly crystalline PTFE by rapid stretching); accord *In re Fine*, 837 F.2d at 1074, 5 U.S.P.Q.2d at 1599.

In addition to not teaching or suggesting all of the elements of the claimed invention of base claim 12, Young does not provide any motivation of select one of seven distinct additives to the enzyme rather than all of the recited seven additives, each of which is indicated to be part of the carefully calibrated mixture. See C.2. Young clearly suggests that all seven additives are part of the mixture that, together, prolongs the enzymes shelf life. The skilled person aware of Young would not have been motivated to attempt a method for storing an enzyme that encompasses adding to the enzyme a single additive of the list recited by Young, with any reasonable expectation of the resulting stored enzyme showing no loss or less than 20% loss of activity after prolonged storage.

Rather, the skilled artisan would have expected that omitting all but one of the additives would destroy the functionality of the mixture. If a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See *In re Fritch*, 972 F.2d at 1265 n.12, 23 U.S.P.Q.2d at 1783 n.12972 F.2d 1260, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992) ("A proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose."); *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959) (holding the suggested combination of references improper under ' 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate").

Overall, far from providing a motivation to combine, modifying the prior art in an effort to attain the claimed invention causes the art itself to become inoperable and destroys its

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intended function. In view of the lack of a *prima facie* showing of obviousness, Applicants submit that the Office has not met its burden and respectfully request withdrawal of the rejection of claims 12, 15, 23 and 24 under 35 U.S.C. §103(a) as being unpatentable over Young is respectfully requested.

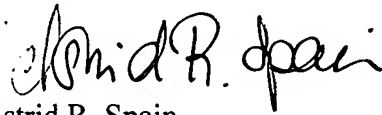
## CONCLUSION

In light of the Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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